

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No. : 10/679,763
Filed : October 6, 2003
Applicant : Barry M. Yomtov, et al.
Title : Medical Device for Neural Stimulation and
Controlled Drug Delivery

TC/AU : 3762
Examiner : Terri L. Smith

Docket No. : 17509-0072
Customer No. : 29052

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, John T. Santini Jr., hereby declare that:

1. I am the President and CEO of MicroCHIPS, Inc., which is the assignee of the above-identified patent application. I have a Ph.D. in chemical engineering from Massachusetts Institute of Technology and over 13 years of experience in the development of micro-reservoir based devices for the protection and selective exposure or release of chemicals, such as pharmaceuticals, diagnostic reagents, or enzymes on biosensors. I am an inventor on 18 issued U.S. patents directed to this technology.

2. I have reviewed the Office Action mailed December 19, 2006, in connection with the present patent application. I also have reviewed U.S. Patent Publication No. 2002/0111601 by Thompson (hereinafter "Thompson") upon which the Examiner relies to reject claims 1-3, 5-

7, 12-17, 20-28 and 31-36. The Examiner's rejection of the claims of the present application appears to be based upon a gross misunderstanding of the teaching of Thompson.

3. The instant claims require, in pertinent part, means for disintegrating a reservoir cap by electrothermal ablation. The structure of the device provides that "when an effective amount of an *electrical current is applied through the leads and reservoir cap*, the temperature of the reservoir cap is locally increased due to **resistive heating**, and the heat generated within the reservoir cap increases the temperature sufficiently to cause the reservoir cap to be electrothermally ablated (i.e., ruptured)." See, e.g., page 14, line 12-29. Thus, reservoir cap rupture is analogous to the failure of a conventional electrical fuse by excessive resistive heating. Thompson cannot remotely be construed to teach this.

4. Thompson discloses only an *electrochemical* mechanism for causing a cap member to be disintegrated. That mechanism is both structurally and functionally distinct from Applicants' electrothermal ablation mechanism. The two mechanisms are neither identical nor equivalent. In the electrochemical mechanism, a voltage potential is created between an anodic cap member and a cathode conductor that is electrically and mechanically isolated from the cap member. This causes *electrons to pass through a conductive solution* (e.g., an *in vivo* aqueous fluid) to complete a circuit, which causes the cap member to oxidize and dissolve into the conductive solution. See Paragraphs 0069 through 0071. The Thompson disintegration mechanism involves neither resistive heating nor electrothermal ablation.

5. The Examiner erroneously characterizes the structure in Figure 6 of Thompson (Office Action, p. 3, ¶ 3) in attempting to show that the reference teaches the claimed reservoir cap structure and means for electrothermal ablation. In particular, the Examiner alleges that

Applicants' means for actively disintegrating the reservoir cap "can comprise "an input lead (e.g. 280, conductor lead) and an output lead (e.g. 286 conductor) each connected to the reservoir (e.g., as shown in Fig. 6 at the designated elements)...." That is incorrect. Thompson clearly teaches that cathode conductor 286 is not connected to the cap 270. See Paragraph 0069 ("Each of these additional cathode conductors ... 284 and 286, are located adjacent to, but **electrically and mechanically isolated from**, a respective reservoir.").

6. Thompson does not teach any type of reservoir cap disintegration mechanism that remotely can be construed to involve disintegration by resistive heating or electrothermal ablation as defined in the instant application. Thompson fails to disclose, suggest, or enable the application of an electrical current directly through a reservoir cap (or cap member) in an amount effective to cause the cap to heat and disintegrate. Therefore, one skilled in the art would not construe Thompson to teach or suggest the elements and features of the claims of the instant application.

7. I declare that all statements made herein of my own knowledge and belief are true and that all statements made on information and belief are believed to be true, and further that the statements are made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

March 19, 2007
Date


John T. Santini Jr., Ph.D.